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§21–2C–08.

- (a) On or before December 31, 2020, the Board shall:
- (1) Collect and review publicly available information regarding prescription drug product manufacturers, health insurance carriers, health maintenance organizations, managed care organizations, wholesale distributors, and pharmacy benefits managers; and
- (2) (i) Identify states that require reporting on the cost of prescription drug products; and
- (ii) Initiate a process of entering into memoranda of understanding with the states identified under item (i) of this item to aid in the collection of transparency data for prescription drug products.
- (b) Based on the information collected under subsection (a)(1) of this section and obtained through memoranda of understanding under subsection (a)(2) of this section, the Board, in consultation with the Stakeholder Council, shall adopt regulations to:
- (1) Establish methods for collecting additional data necessary to carry out its duties under this subtitle; and
- (2) Identify circumstances under which the cost of a prescription drug product may create or has created affordability challenges for the State health care system and patients.
- (c) The Board shall use the information collected under subsection (a)(1) of this section and obtained through memoranda of understanding under subsection (a)(2) of this section to identify prescription drug products that are:
- (1) Brand name drugs or biologics that, as adjusted annually for inflation in accordance with the Consumer Price Index, have:
- (i) A launch wholesale acquisition cost of \$30,000 or more per year or course of treatment; or
- (ii) A wholesale acquisition cost increase of \$3,000 or more in any 12-month period, or course of treatment if less than 12 months;

- (2) Biosimilar drugs that have a launch wholesale acquisition cost that is not at least 15% lower than the referenced brand biologic at the time the biosimilars are launched:
- (3) Generic drugs that, as adjusted annually for inflation in accordance with the Consumer Price Index, have a wholesale acquisition cost:

(i) Of \$100 or more for:

- 1. A 30-day supply lasting a patient for a period of 30 consecutive days based on the recommended dosage approved for labeling by the United States Food and Drug Administration;
- 2. A supply lasting a patient for fewer than 30 days based on the recommended dosage approved for labeling by the United States Food and Drug Administration; or
- 3. One unit of the drug if the labeling approved by the United States Food and Drug Administration does not recommend a finite dosage; and
- (ii) That increased by 200% or more during the immediately preceding 12—month period, as determined by the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition cost reported over the immediately preceding 12 months; and
- (4) Other prescription drug products that may create affordability challenges for the State health care system and patients, in consultation with the Stakeholder Council.

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